

## CLAIMS

### WHAT IS CLAIMED IS:

1. A neuro-stimulation system, comprising:

an electrode array having an implantable support member configured to be implanted into a patient and a plurality of therapy electrodes carried by the support member;

a pulse system operatively coupled to the therapy electrodes, the pulse system delivering a stimulus to the therapy electrodes; and

a controller operatively coupled to the pulse system, the controller including a computer operable medium containing instructions that generate command signals that define the stimulus delivered by the pulse system and determine a desired configuration for the therapy electrodes and/or a desired stimulus to be delivered to the therapy electrodes based upon feedback input to the controller.

2. The system of claim 1 wherein the therapy electrodes are independently coupled to the pulse system such that the pulse system can activate and/or deactivate individual therapy electrodes.

3. The system of claim 1 wherein the pulse system and the electrode array are components of an integrated unit configured to be implanted in the patient at a stimulation site.

4. The system of claim 1 wherein the electrode array is configured to be implanted at a stimulation site in the patient and the pulse system is separate

from the electrode array and configured to be implanted at a site in the patient remote from the stimulation site, and the pulse system being coupled to the electrode array by a conductive line implanted in the patient.

5. The system of claim 1 wherein the controller is configured to be external to the patient and the pulse system is configured to be implanted in the patient, and wherein the pulse system is linked to the controller via a direct link or an indirect link such that the controller can direct the pulse system to activate and/or deactivate the electrodes independently.

6. The system of claim 1, further comprising a sensing device configured to be attached to a sensing location of the patient, the sensing device generating response signals defining the feedback input into the controller; and wherein the computer operable medium contains instructions that evaluate the response signals from the sensing device.

7. The system of claim 6 wherein the sensing device comprises a sense electrode configured to be attached to the patient at a sense location to sense a response to the stimulus applied to the therapy electrodes.

8. The system of claim 6 wherein the sensing device comprises a sense electrode configured to be attached to the patient at a sense location and an EMG unit coupled to the sense electrode.

9. The system of claim 6 wherein the sensing device comprises a functional MRI device that detects locations of neural-activity in the brain.

10. The system of claim 6 wherein the computer operable medium of the controller comprises a computer readable medium containing instructions causing the controller to perform the following method:

applying an electrical stimulus having a plurality of stimulus parameters to a selected configuration of the therapy electrodes;

sensing a response to the applied electrical stimulus using the sensing device;

determining whether the response is within a desired range or an improvement over a previous sensed response from a different electrical stimulus and/or a different configuration of therapy electrodes;

selecting an alternate configuration of the therapy electrodes and/or an alternate electrical stimulus;

repeating the applying, sensing, determining and selecting procedures using the alternate configuration of the therapy electrodes and/or the alternate electrical stimulus; and

choosing a configuration of therapy electrodes and/or an electrical stimulus corresponding to a sensed response that is within a desired range and/or is an improvement compared to other sensed responses.

11. The system of claim 6 wherein the computer operable medium of the controller comprises a computer readable medium containing instructions causing the controller to perform the following method:

sending a command signal from the controller to the pulse system;

delivering an electrical pulse from the pulse system to a configuration of the therapy electrodes;

sensing a response to the electrical pulse using the sensing device;

receiving a response signal from the sensing device at the controller;

in the controller, determining whether the signal is within a desired range or an improvement over a previous response signal from another electrical pulse and/or another configuration of the therapy electrodes, and selecting an alternate configuration of the therapy electrodes and/or an alternate electrical pulse;

repeating the sending, delivering, sensing, receiving, and determining procedures using the alternate configuration of therapy electrodes and/or the alternate electrical pulse; and

in the controller, identifying an effective pulse therapy electrode configuration and/or electrical pulse; and

storing the effective therapy electrode configuration and/or electrical parameter in a memory of the controller.

12. The system of claim 6 wherein the computer operable medium of the controller comprises a computer readable medium containing instructions causing the controller to perform the following method:

installing the electrode array at a therapy site of a patient;

installing the sensing device at a sense location of the patient;

selecting a setup configuration of the therapy electrodes and a control stimulus of electrical parameters;

applying the control stimulus to the therapy electrodes;

sensing a response in the patient with the sensing device and generating a response signal;

in the controller, evaluating the response signal by comparing the response signal with at least one of a desired response signal and/or an antecedent response signal sensed by the sensing device that have been stored in a memory of the controller;

in the controller, automatically choosing an alternate configuration of therapy electrodes according to the evaluation of the response signal with the desired response signal and/or the antecedent response signal;

reapplying the control stimulus to the alternate configuration of therapy electrodes and sensing a response signal using the sensing device;  
and

repeating the evaluating, choosing and reapplying procedures until the response signal is within a desired range and/or a desired number of therapy electrode configurations have been tested.

13. The system of claim 6 wherein the computer operable medium of the controller comprises a computer readable medium containing instructions causing the controller to perform the following method:

installing the electrode array at a therapy site of a patient;

installing the sensing device at a sense location of the patient;

applying an electrical stimulus having a plurality of stimulus parameters to a control configuration of therapy electrodes;

sensing a response in the patient with the sensing device and generating a response signal;

in the controller, evaluating the response signal by comparing the response signal with at least one of a desired response signal and/or an

antecedent response signal sensed by the sensing device stored in a memory of the controller;

in the controller, automatically choosing an alternate set of stimulus parameters according to the evaluation of the response signal with the desired response signal and/or the antecedent response signal;

reapplying the alternate set of stimulus parameters to the setup configuration of therapy electrodes and sensing a response signal using the sensing device; and

repeating the evaluating, choosing and reapplying procedures until the response signal is within a desired range and/or a desired number of stimulus parameters have been tested.

14. The system of claim 6 wherein the computer operable medium of the controller comprises a computer readable medium containing instructions causing the controller to perform the following method:

selecting an initial set of stimulation parameters for an initial electrical stimulus;

applying the initial electrical stimulus to a configuration of the therapy electrodes at a target stimulation site of the patient;

sensing a response signal at a sensing site of the patient that corresponds to the initial electrical stimulus applied to the therapy electrodes;

independently adjusting a current intensity until a threshold electrical stimulus is identified, the threshold electrical stimulus having a threshold current intensity at which a response is first identified in a population of neurons of the target site; and

applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus.

15. In a computer, a method of automatically determining a favorable neuro-stimulation program for a patient, comprising:

applying an electrical stimulus having a plurality of stimulus parameters to a selected configuration of the therapy electrodes that have been installed at a target therapy site of a patient;

sensing a response to the applied electrical stimulus at a sensing device that has been installed at a sense location of the patient;

determining whether the response is within a desired range or an improvement over a previous sensed response from a different electrical stimulus and/or a different configuration of therapy electrodes;

selecting an alternate configuration of therapy electrodes and/or an alternate electrical stimulus;

repeating the applying, sensing, determining and selecting procedures using the alternate configuration of therapy electrodes and/or the alternate electrical stimulus; and

choosing a configuration of therapy electrodes and/or an electrical stimulus corresponding to a sensed response that is within a desired range and/or provides a better result compared to other sensed responses.

16. The method of claim 15 wherein the selecting procedure comprises computing an alternate stimulus parameter while maintaining a constant electrode

configuration, and wherein computing the alternate stimulus parameter comprises correlating a plurality of different stimuli applied to the constant electrode configuration with corresponding sensed responses to determine a stimulus/response trend and estimating a new stimulus parameter that is expected to improve the efficacy according to the stimulus/response trend.

17. The method of claim 15 wherein the selecting procedure comprises computing an alternate electrode configuration while maintaining constant stimulus parameters, and wherein computing the alternate electrode configuration comprises correlating a plurality of sensed responses with corresponding electrode configurations to which the constant stimulus parameters were applied to determine an electrode-configuration/response trend and estimating a new electrode configuration that is expected to improve the efficacy according to the electrode-configuration/response trend.

18. The method of claim 15 wherein the selecting procedure comprises increasing a stimulus parameter when a stimulus/response trend indicates that an increase in the stimulus parameter improves the efficacy of the stimulus.

19. The method of claim 15 wherein the selecting procedure comprises decreasing a stimulus parameter when a stimulus/response trend indicates that a decrease in the stimulus parameter improves the efficacy of the stimulus.

20. The method of claim 15 wherein the applying, sensing, determining, selecting, repeating and choosing procedures are repeated on the same patient within a period not greater than one week.

21. The method of claim 15 wherein the applying, sensing, determining, selecting, repeating and choosing procedures are repeated on the same patient on consecutive days.



22. The method of claim 15 wherein the applying, sensing, determining and selecting procedures are completed in a time period not greater than approximately 300 seconds.

23. The method of claim 15 wherein two iterations of the applying, sensing, determining and selecting procedures are repeated in a time period not greater than approximately 90 seconds.

24. The method of claim 15 wherein two iterations of the applying, sensing, determining and selecting procedures are repeated in a time period not greater than approximately 180 seconds.

25. The method of claim 15 wherein two iterations of the applying, sensing, determining and selecting procedures are repeated in a time period of approximately 20-90 seconds.

26. The method of claim 15 wherein a single iteration of the applying, sensing, determining and selecting procedures is completed in a time period not greater than approximately 45 seconds.

27. The method of claim 15 wherein a single iteration of the applying, sensing, determining and selecting procedures is completed in a time period of approximately 10-30 seconds.

28. The method of claim 15 wherein the sensing procedure comprises attaching EMG sensors to a sense site of the patient, detecting peripheral responses to the stimuli applied to the electrodes, and automatically sending the detected peripheral responses to the controller.

29. The method of claim 15 wherein the sensing procedure comprises detecting data related to neural activity using a functional MRI and automatically sending the data to the controller.

30. The method of claim 15 wherein the data comprises coordinates of neural activity relative to the therapy electrodes.

31. The method of claim 15 wherein the data comprises intensity levels of neural activity.

32. In a computer, a method of automatically determining a favorable a neuro-stimulation program for a patient, comprising:

sending a command signal from a controller to a pulse system operatively coupled to the controller;

delivering an electrical pulse from the pulse system to a configuration of therapy electrodes in a therapy electrode array installed at a target stimulation site of a patient;

sensing a response to the electrical pulse at a sensing device installed at a sense location of the patient;

receiving a response signal from the sensing device at the controller;

in the controller, determining whether the signal is within a desired range or an improvement over a previous response signal from another electrical pulse and/or another configuration of therapy electrodes, and selecting an alternate configuration of therapy electrodes and/or an alternate electrical pulse;

repeating the sending, delivering, sensing, receiving, and determining procedures using the alternate configuration of therapy electrodes and/or the alternate electrical pulse; and

in the controller, identifying an effective pulse therapy electrode configuration and/or electrical pulse; and

storing the effective therapy electrode configuration and/or electrical pulse in a memory of the controller.

33. The method of claim 32 wherein the selecting procedure comprises computing an alternate stimulus parameter while maintaining a constant electrode configuration, and wherein computing the alternate stimulus parameter comprises correlating a plurality of different stimuli applied to the constant electrode configuration with corresponding sensed responses to determine a stimulus/response trend and estimating a new stimulus parameter that is expected to improve the efficacy according to the stimulus/response trend.

34. The method of claim 32 wherein the selecting procedure comprises computing an alternate electrode configuration while maintaining constant stimulus parameters, and wherein computing the alternate electrode configuration comprises correlating a plurality of sensed responses with corresponding electrode configurations to which the constant stimulus parameters were applied to determine an electrode-configuration/response trend and estimating a new electrode configuration that is expected to improve the efficacy according to the electrode-configuration/response trend.

35. The method of claim 32 wherein the selecting procedure comprises increasing a stimulus parameter when a stimulus/response trend indicates that an increase in the stimulus parameter improves the efficacy of the stimulus.

36. The method of claim 32 wherein the selecting procedure comprises decreasing a stimulus parameter when a stimulus/response trend indicates that a decrease in the stimulus parameter improves the efficacy of the stimulus.

37. The method of claim 32 wherein two iterations of the applying, sensing, determining and selecting procedures are repeated in a time period not greater than approximately 90 seconds.

38. The method of claim 32 wherein two iterations of the applying, sensing, determining and selecting procedures are completed in a time period not greater than approximately 180 seconds.

39. The method of claim 32 wherein the sensing procedure comprises attaching EMG sensors to a sense site of the patient, detecting peripheral responses to the stimuli applied to the electrodes, and automatically sending the detected peripheral responses to the controller.

40. The method of claim 32 wherein the sensing procedure comprises detecting data related to neural activity using a functional MRI and automatically sending the data to the controller.

41. A method of automatically determining a favorable neuro-stimulation program for a patient, comprising:

installing an electrode array having a plurality of therapy electrodes at a therapy site of a patient;

installing a sensing device at a sense location of the patient;

selecting a setup configuration of therapy electrodes and a control stimulus of electrical parameters;



sensing a response in the patient with the sensing device and generating a response signal;

in the controller, evaluating the response signal by comparing the response signal with at least one of a desired response signal and/or an antecedent response signal sensed by the sensing device stored in a memory of the controller;

in the controller, adjusting at least one of the stimulus parameters according to the evaluation of the response signal with the desired response signal and/or the antecedent response signal;

reapplying the adjusted stimulus parameters to the setup configuration of therapy electrodes and sensing a response signal using the sensing device; and

repeating the evaluating, choosing and reapplying procedures until the response signal is within a desired range and/or a desired number of stimulus parameters have been tested.

43. A method of automatically determining a favorable sub-threshold neuro-stimulation program for a patient, comprising:

selecting a set of stimulation parameters for an electrical stimulus;

applying the electrical stimulus to a configuration of therapy electrodes at a target stimulation site of the patient;

sensing a response signal at a sensing site of the patient that corresponds to the electrical stimulus applied to the therapy electrodes;

independently adjusting a current intensity until a threshold electrical stimulus is identified, the threshold electrical stimulus having a

threshold current intensity at which a response is first identified in a population of neurons of the target site; and

applying a sub-threshold electrical stimulus to the configuration of therapy electrodes, the sub-threshold electrical stimulus having a current intensity less than the current intensity of the threshold electrical stimulus.

44. The method of claim 43 wherein applying a sub-threshold stimulus comprises applying a sub-threshold current intensity of approximately 40-99% of the threshold current intensity.

45. The method of claim 43 wherein applying a sub-threshold stimulus comprises applying a sub-threshold current intensity of approximately 60-80% of the threshold current intensity.

46. The method of claim 43 wherein applying a sub-threshold stimulus comprises applying a sub-threshold current intensity of approximately 68-72% of the threshold current intensity.

47. The method of claim 43 wherein:

applying a sub-threshold stimulus comprises applying a sub-threshold current intensity of approximately 40-99% of the threshold current intensity; and

the method further comprises determining whether the application of the sub-threshold current intensity decreased a membrane activation threshold for a population of neurons subject to the sub-threshold stimulus.

48. The method of claim 43, further comprising decreasing the sub-threshold current intensity to a lower level and re-applying the decreased sub-threshold stimulus with the lower current intensity to the neurons, and further determining whether the application of the decreased sub-threshold current intensity further decreased the membrane activation threshold for the population of neurons.

49. The method of claim 43, further comprising repeating (a) decreasing the sub-threshold current intensity to a lower level, (b) re-applying the decreased sub-threshold stimulus with the lower current intensity to the neurons, and (c) further determining whether the application of the decreased sub-threshold current intensity further decreased the membrane activation threshold for the population of neurons until the membrane activation threshold does not decreased by a desired amount.